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The Subcutaneous Defibrillator

A Review of the Literature

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The recently commercially available subcutaneous implantable cardioverter-defibrillator (S-ICD) uses a completely subcutaneous electrode configuration to treat potentially lethal ventricular tachyarrhythmia. Clinical trials have proven its effectiveness in detecting and treating ventricular fibrillation and tachycardia. The S-ICD offers the advantage of eliminating the need for intravenous and intracardiac leads and their associated risks and shortcomings. However, its major disadvantage is its inability to provide bradycardia rate support and antitachycardia pacing to terminate ventricular tachycardia. This paper discusses the S-ICD clinical trials and advantages and disadvantages of this novel technology to help the physician identify its role and select candidate patients who will benefit from this device. (J Am Coll Cardiol 2014;63:1473–9) © 2014 by the American College of Cardiology Foundation

Sudden cardiac death (SCD) affects 350,000 individuals each year, accounting for half of all cardiac deaths in developed countries (1). The introduction of the implantable cardioverter-defibrillator (ICD) into clinical practice over the past 25 years has provided life-saving therapy as primary and secondary prevention of SCD to more than 1 million patients worldwide (2). ICD technology evolved from devices that delivered therapy through epicardial patch electrodes introduced by thoracotomy to those using transvenous leads advanced to the right ventricle for detection and treatment of tachyarrhythmia and to provide bradycardia-pacing support. The transvenous ICD (T-ICD) reduced the morbidity and risk associated with thoracotomy implants. However, use of transvenous leads involves potential complications including hemopericardium, hemothorax, pneumothorax, lead dislodgement, lead malfunction, device-related infection, and venous occlusion (3).

Lead malfunction caused by conductor failure or insulation breach occurs in up to 40% of indwelling transvenous leads at 8 years after implantation (4). Failure occurs more commonly in active young patients or in patients with longer life expectancy who expose the leads to greater cumulative physical stress. Longer-living ICD patients may also undergo several generator exchanges, each with an associated risk of pocket infection reaching up to 3%. Because lead malfunction may necessitate, and device infection usually requires, extraction of the lead, use of transvenous pacing and defibrillating leads introduces the potential risk of extraction-associated morbidity and mortality (5) to patients with chronically present transvenous leads.

Initial attempts to avoid the use of an endovascular defibrillating system in pediatric patients, patients with difficult or absent venous access, and patients at high risk of bacteremia (i.e., patients with chronic indwelling catheters) involved the use of ICD systems with nontransvenous defibrillating components (6–8). However, those early devices still relied on epicardial or transvenous pacing systems for ventricular sensing for arrhythmia detection. The need to completely avoid venous access issues, endovascular mechanical stress producing lead malfunction, and extraction-associated risks led to the development of the entirely subcutaneous ICD (S-ICD). Its unique design avoids endovascular leads, thus eliminating many of the complications associated with the traditional T-ICD. The novel device, developed and tested over the past decade, gained approval as accepted therapy for detection and termination of ventricular arrhythmias. The European Union approved its use in 2009; the U.S. Food and Drug Administration approved it in 2012. Worldwide, implants over the past 2 years exceed 2,000 units.

S-ICD System

The S-ICD system (model SQ-RX 1010, Cameron Health, Inc., San Clemente, California) includes a dedicated external programmer, a subcutaneous pulse generator enclosed in a titanium case, and a single subcutaneous electrode containing both sensing and defibrillating components. The lead is composed of a proximal and a distal sensing electrode positioned adjacent to either end of a 3-inch defibrillation coil electrode. The recommended position for the pulse

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Abbreviations and Acronyms

DFT = defibrillation threshold

ICD = implantable cardioverter-defibrillator

SCD = sudden cardiac death

S-ICD = subcutaneous implantable cardioverter-defibrillator

T-ICD = transvenous implantable cardioverter-defibrillator

VF = ventricular fibrillation

VT = ventricular tachyarrhythmia

generator involves a subcutaneous pocket created over the fifth intercostal space between the mid and anterior axillary lines. The subcutaneous lead should lie parallel to the left side of the sternum, with its upper pole anchored at the level of the sternal notch and the lower electrode anchored just below the level of the xiphoid process. The electrode then makes a right-angle turn laterally to enter the pulse generator pocket (Figs. 1A and 1B). Implantation of the device relies exclusively on anatomical landmarks, with the option to confirm defibrillating electrode position by fluoroscopy.

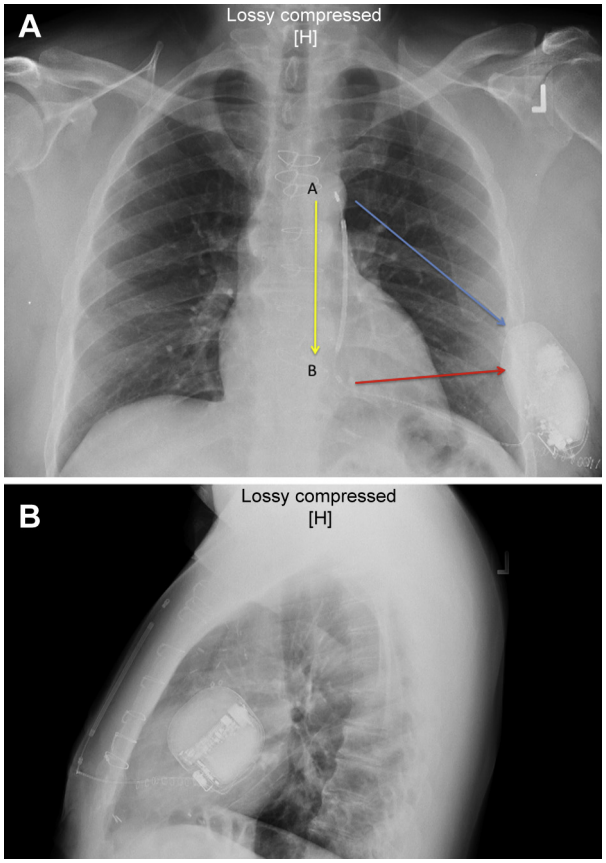

Figure 1 PA and Lateral Chest Radiographs of a Patient With an S-ICD

The 3 sensing vectors are expressed as arrows of different colors: the primary vector **(red)** is between the lower electrode and the ICD scan; the secondary vector **(blue)** is the upper electrode (lead tip) and ICD scan; and the alternate vector **(yellow)** is lead tip to base. PA = posteroanterior; S-ICD = subcutaneous implantable cardioverter-defibrillator.

The S-ICD system detects changes in ventricular rate by using modified subsurface electrocardiography through either a primary, secondary, or alternate vector (Fig. 1A). The device uses proprietary algorithms to automatically determine the optimal sensing vector based on an R- to T-wave ratio that avoids double QRS counting or T-wave oversensing. It measures the heart rate as the rolling average of 4 consecutive sensed intervals, recognizing ventricular fibrillation (VF) when 18 of 24 consecutive sensed events exceed a pre-determined nonprogrammable detection zone limit. The device then charges its capacitors to deliver a biphasic-waveform defibrillating pulse of up to 80 J. The S-ICD can provide post-shock bradycardia ventricular pacing support for 30 s (Fig. 2).

The current pulse generator weighs 145 g and has a volume of 69 ml (Fig. 3). The manufacturer estimates longevity of the battery to be 5 years (9).

S-ICD Clinical Trials

Bardy et al. (10) summarized the early clinical testing experience with the S-ICD, from acute studies to test the optimal sensing and defibrillation configuration, to the initial long-term follow-up of fully functional devices. The first acute evaluation identified the optimal defibrillation configuration as a combination of parasternal electrode and left lateral thoracic pulse generator. A comparison of the S-ICD defibrillation system with a T-ICD in 2004 (n = 49) found that the S-ICD equally terminated induced VF, although at a higher defibrillation threshold (DFT) than that of the T-ICD (36.6 ± 19.8 J vs. 11.1 ± 8.5 J, respectively). A pilot study in 2008 (n = 6) showed that the implanted S-ICD effectively detected and terminated 2 consecutive episodes of induced VF acutely with no inappropriate shocks or device complications during a 488 ± 2 day follow-up. An expanded evaluation (n = 55) showed that the device terminated induced VF at implant with 98% efficacy but also detected and terminated 12 episodes of spontaneous ventricular tachycardia (VT)/VF in 3 patients. However, 3 patients experienced inappropriate sensing due to muscle noise, 6 patients experienced lead migration/dislodgement, and 2 patients developed device infection.

Dabiri Abkenari et al. (11) reported a single-center European experience (n = 31) with the S-ICD in which the device detected and terminated 100% of induced VF episodes. Additionally, 4 patients with spontaneous VF/VT received successful therapy during follow-up; 5 patients received inappropriate shocks; and 2 patients experienced lead migration that required operative repositioning.

A multicenter trial from the Netherlands (n = 118) conducted between 2008 and 2011 reported a 177–patient-year follow-up (12). The S-ICD successfully detected 9 episodes of spontaneous VT and 36 episodes of spontaneous VF in 8 patients. It successfully treated 98% of these episodes (1 VT episode accelerated into VF and terminated before delivery of a second shock). However, 13% of patients

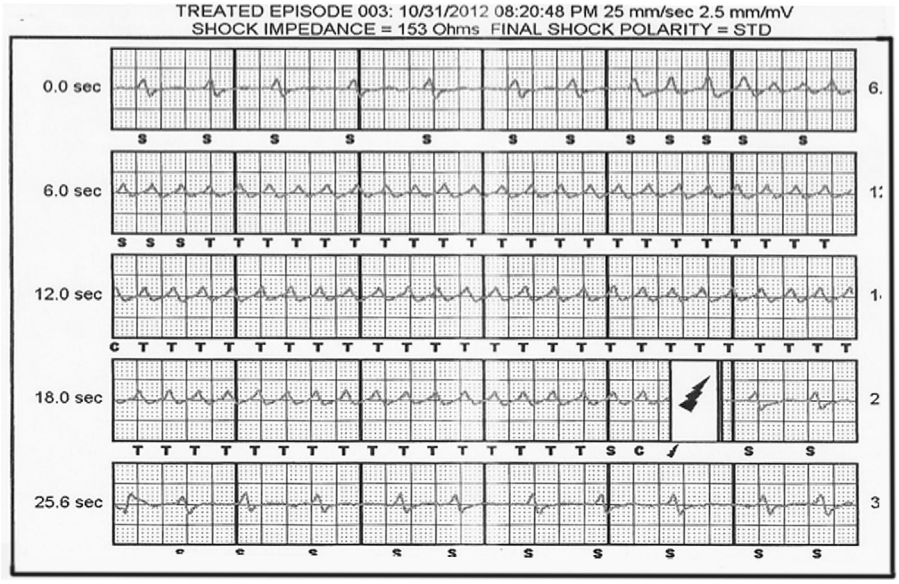

Figure 2 **Appropriate ICD Shock**

An electrogram from a patient with an S-ICD who received a shock for fast ventricular tachycardia **(lightening symbol)** with restoration of sinus rhythm with premature beats. S-ICD = subcutaneous implantable cardioverter-defibrillator.

experienced inappropriate shocks for multiple reasons: 3 developed lead migration, creating the need to develop a sleeve that anchored the lead as it turned laterally at the subxiphoid level; 2 patients developed skin erosion over the device pocket; and infection occurred in 7 patients, requiring removal of the device. The highest rate of inappropriate shocks and device-related complications occurred in the first 15 implanted devices in each of the centers, suggesting the presence of a learning curve associated with this new technology (12).

Figure 3 **S-ICD Size**

The S-ICD **(middle)** with 2 different T-ICDs from 2 different device manufacturers. Note the larger size of the S-ICD. S-ICD = subcutaneous implantable cardioverter-defibrillator; T-ICD = transvenous implantable cardioverter-defibrillator.

The early UK S-ICD experience (n = 111) included a group mean age of 33 years (range: 10 to 87 years) with primary cardiac electrical heart disease (43%), hypertrophic cardiomyopathy (20%), and ischemic cardiomyopathy (14%) (13). The device detected and treated all induced episodes and all 10 spontaneous episodes of VF and 14 of VT. Complications included device-related infection or skin erosion requiring reoperation in 17% of patients. A total of 15% of patients received inappropriate shocks; younger patients experienced a higher rate of inappropriate shocks because of T-wave oversensing. Another multicenter evaluation of the S-ICD that included a mixed pediatric and adult population also demonstrated inappropriate shocks due to T-wave oversensing in younger patients (5).

The largest multicenter clinical evaluation of the safety and efficacy of the S-ICD enrolled 330 individuals with established indications for an ICD (14). Nine patients withdrew before device implantation, and 17 patients did not undergo DFT testing; 304 enrolled subjects underwent successful implantation and DFT testing. The S-ICD terminated all induced VF episodes. Twenty-one subjects experienced 119 episodes of spontaneous VT/VF, 38 as isolated events and 81 as part of a VT storm. The device successfully terminated 37 of 38 isolated episodes; 1 VT terminated as the device was charging to deliver a second shock. The S-ICD successfully treated all VT storm events.

Forty-one patients (13.1%) received an inappropriate shock; the cause was treatment for supraventricular tachycardia in 16 patients and oversensing in the other 25. Eighteen subjects developed pocket infections (5.6%); 4 required device explantation, and 1 required pocket revision (1.56% rate of intervention for infection).

A recently reported multicenter case control study (n = 69) compared defibrillation efficacy in patients receiving an S-ICD with an age- and sex-matched cohort receiving a T-ICD (15). The S-ICD first shock efficacy in terminating induced VF using a 15-J safety margin was 89.5%, compared to 90.8% with the T-ICD, at a 10-J safety margin (p = 0.8). The success rate with the S-ICD increased to 95.5% after a second shock by using reverse electrode polarity. Another small study (n = 40) reported a first shock efficacy of 58% with an overall shock efficacy of 96% (for induced and spontaneous VF/VT) after additional shocks (16).

Discussion

Development of the S-ICD represents a quantum step in the evolution of ICD technology to prevent SCD. Data from the S-ICD clinical trials support its efficacy and safety in detecting and terminating VT. Although the first-generation device experience included adverse events such as sensing issues that led to inappropriate shocks, lead migration, and device infection, their frequency appears to be within the bounds of clinical experience with T-ICD, and the preponderance of device infection and lead migration early in a center's experience is consistent with a learning curve. The advantages of a nontransvenous ICD system include elimination of complications related to venous access, no physical stress on leads associated with cardiac motion, less morbidity associated with device extraction, and a potential reduction in endovascular infection risk to patients with dialysis access or endovascular prostheses. The limitations of the current S-ICD include its inability to provide antitachycardia pacing for VT, limited bradycardia pacing support, relatively large size and bulk of the pulse generator, and absence of endovascular monitoring capabilities for collateral data gathering such as impedance monitoring for chronic heart failure.

One estimate of potential candidates for the S-ICD might include every patient indicated for primary SCD prevention without a pacing indication. However, the limitations of the current system and the relative paucity of data on long-term performance compared with that of the T-ICD might temper that view (2). The S-ICD appears to be an attractive alternative in relatively young patients (i.e., age <40 years), those at high-risk for bacteremia (due to indwelling catheters/hardware or immune-compromised states), and patients lacking venous access. Without the use of transvenous leads, most major complications associated with their use are avoided. Given that the duration of

Figure 4 Inappropriate ICD Shock

An inappropriate shock delivered by the S-ICD as a result of T-wave oversensing during sinus tachycardia. S-ICD = subcutaneous implantable cardioverter-defibrillator.

implanted leads greatly influences the probability of malfunction, the S-ICD presents an attractive alternative in younger patients with greater longevity, such as those with hypertrophic cardiomyopathy and inherited ion channel abnormalities. The potential advantage of the S-ICD in the young is tempered to some degree by the higher rate of inappropriate shocks seen in this group of patients. No study has prospectively addressed the use of ICD therapy as primary prevention of SCD in the dialysis population; all the clinical trials actively excluded enrolling dialysis patients. The S-ICD clinical evaluation protocols also excluded enrollment of patients with chronic kidney disease requiring dialysis; yet it may provide a safer approach in this group of patients with a greater risk for infection due to access catheters, limited venous access due to scarring, and greater lead extraction-related complications due to increased calcification around implanted leads. Use of the S-ICD should be avoided in patients with either known monomorphic VT or with conditions (sarcoidosis or arrhythmogenic right ventricular cardiomyopathy) likely to result in VT amenable to antitachycardia pacing (17).

The S-ICD system delivers energy to the heart in a more homogenously distributed pattern than the endocardial shock delivered by the T-ICD (18). The uneven distribution of energy across the myocardium after an endocardial shock can produce voltage gradients and electroporation resulting in myocardial stunning and damage (19,20). Endocardial shocks produce significant troponin release; shocks delivered from subcutaneous electrodes do not (21,22). Myocardial injury and stunning associated with ICD discharge might explain the increased mortality seen in heart failure patients receiving multiple shocks (23,24). Whether the lack of significant troponin release after a subcutaneous shock constitutes an advantage the S-ICD and whether it translates into a survival benefit remain to be determined.

The use of a subcutaneous sensing electrode with the S-ICD may theoretically increase the risk of oversensing noise or myopotential signals and undersensing low-amplitude cardiac signals during VF. The START (Subcutaneous vs. Transvenous Arrhythmia Recognition Testing) trial compared arrhythmia detection of 3 commercially available T-ICD lead systems versus the S-ICD electrode (25). All devices excelled in detecting ventricular tachyarrhythmia (100%); however, the S-ICD demonstrated greater specificity in discriminating supraventricular from ventricular tachycardia (98% S-ICD vs. 76.7% single-chamber T-ICD vs. 68% dual-chamber T-ICD).

The rate of inappropriate shocks observed in the S-ICD trials ranged from 5% to 25% (Table 1), a frequency similar to the observed rate reported in earlier trials of the T-ICD (26). However, more recent T-ICD trials show that newer algorithms reduce the rate of inappropriate shocks to less than 5% (24), suggesting an advantage of T-ICDs over the current S-ICD. Ideally, greater user programming experience and improvements in S-ICD technology may reduce the rate of inappropriate shocks (14).

Table 1 A Summary of Different S-ICD Trials

	Parameter	Bardy et al. (10)	Olde Nordkamp et al. (12)	Kobe et al. (15)	Jarman et al. (13)	Aydin et al. (16)	Dabiri Abkenari et al. (11)	Weiss et al. (14)
No. of patients		55	118	69	111	40	31	330 enrolled (321 implant attempted)
Patient follow-up, mean ± SD		10 ± 1 months	18 ± 7 months	217 ± 138 days	12.7 ± 7.1 months	229 days	—	330 days
Outcomes	Successful termination: induced VF	52 (98%)	—	64 (95.5 %)	111 (100%)	39 (97.5%)	31 (100%)	304 of 304 (100%)
	Successful termination: spontaneous VF/VT (patients)	3 (100%)	8 (100%)	3 (100%)	13 (100%)	4 (100%)	4 (100%)	20 of 21 (95.2%)
Complications	Infection	2 (3.6%)	7 (5.9%)	1 (1.4%)	11 (9.9%)	—	—	18 (5.6%)
	Lead migration/dislodgement	6 (10.9%)	3 (2.5%)	—	—	—	2 (6.5%)	—
	Rate of inappropriate shocks	5 (9%)	15 (13%)	5(7.2%)	17 (15%)	2 (5%)	5 (16.1%)	41 (13.1%)

S-ICD = subcutaneous implantable cardioverter-defibrillator; VF = ventricular fibrillation; VT = ventricular tachyarrhythmia.

An increased ventricular rate during atrial arrhythmia constitutes the major cause of inappropriate shocks delivered by T-ICD systems. However, oversensing T waves or myopotential signals produces most inappropriate S-ICD shocks (Fig. 4) (13,26,27). Inappropriate shocks occur more frequently in younger, physically active patients, the group most likely to benefit from the features of the S-ICD system (5,13). The addition of a second tachycardia zone to S-ICD programming may significantly reduce the rate of inappropriate shocks (14).

The rate of infection with S-ICD systems ranges up to 10% of implants (13). The larger studies to date reported similar rates of infection (5.9% [12] and 5.6% [27]). One study advocated the adequacy of conservative treatment with a low need for intervention (1.56%) (27); yet, another study reported a greater need for surgical intervention or device removal (13). The rate of pocket infection with the S-ICD exceeds that with the T-ICD. The 3 incisions required for S-ICD implantation provide a greater probability for bacterial entry. Also, the increased bulk of the S-ICD may exert more pressure on the skin and increase the risk of tissue necrosis and erosion. The infection rate may decrease with more operator experience, introduction of smaller pulse generators, and use of a 2-incision technique for system implantation (28).

Other limitations of the S-ICD typify the first-generation nature of the current device: lack of continuous demand and antitachycardia pacing contraindicates the use of the S-ICD in patients with sinus node dysfunction, atrioventricular block, or an indication for cardiac resynchronization. Because 80% of spontaneous VT episodes respond to painless antitachycardia pacing (17), patients with a history of VT benefit more from a T-ICD (23,29). The longevity of the S-ICD battery is estimated at 5 years compared with the most recently introduced single-lead T-ICD that may exceed 10 years. In addition, the S-ICD system lacks remote monitoring capability, a feature that improves patient outcomes and simplifies follow-up (30,31).

Conclusions

The clinical experience from the introduction of the S-ICD system underscores its role as a reliable alternative for preventing SCD. The exclusive use of a subcutaneous lead for sensing and defibrillation represents the greatest advantage of this novel technology; the S-ICD eliminates the drawbacks associated with endovascular electrodes. However, the lack of demand bradycardia or anti-tachycardia pacing limits its utility in patients with conduction system disease or pace-terminable VT. The first-generation device raises concerns about an increased risk of pocket infection, battery longevity, and inappropriate shocks compared with the newest T-ICD systems. No study to date directly compared the T-ICD and the S-ICD in patients indicated for ICD therapy as primary prevention of SCD. The clinical experience does suggest that its use be considered in relatively younger patients (i.e., age <40 years), those at increased risk for bacteremia, patients with indwelling intravascular hardware at risk for endovascular infection, or in patients with compromised venous access. As seen with other early examples of evolutionary technology, improvements in design and manufacture will improve upon some of the drawbacks of a first-generation device.

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